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Public Information and Records Integrity Branch (PIRIB)
Office of Pesticide Programs (OPP)
Environmental Protection Agency (7502C)
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460-0001

Attention: Docket ID Number OPP-2002-49

The United States Environmental Protection Agency (US.EPA) issued a Federal Register Notice announcing the availability and opportunity for public comment on the "Preliminary Comparative Ecological Assessment for Nine Rodenticides". The Notice was issued on January 29, 2003, with a 60-day public comment period ending March 31, 2003.

We wish to have the following comments entered into public record:

1. The Preliminary Comparative Ecological Assessment (PCEA) makes no mention of the benefits of the Rodenticides evaluated and leads readers to focus only on their potential risks. FIFRA § 2(bb) requires that the US.EPA must take into account the economic, social, and environmental costs and benefits of the use of any pesticide when evaluating whether risks are unreasonable to man or the environment.
2. The PCEA does not discuss how the results of the analysis will be used in a regulatory context or what specific steps that the US.EPA intends to take as a result of the risk assessment.
3. Although conclusions are made regarding risks to birds and non-target mammals, the PCEA does not include a quantitative exposure assessment. In fact, it is stated in the PCEA Executive Summary that "In preliminary risk assessments, an assumption is made that birds and non-target mammals are likely to be exposed to the pesticide without attempting to establish a quantitative measure of likelihood". Without a quantitative exposure assessment, risks should not be described as high, moderate, or low (as in Table 47) because only relative or comparative risks, and not absolute risks, have been evaluated.
4. Despite providing summaries of target species residue data for most of the Rodenticides active ingredients evaluated (Tables 11 and 15), US.EPA did not use this information for assessing secondary risks to birds or non-target mammals.
5. The methodology used in the PCEA does not adequately take into account the different use patterns, use sites, application methods, exposure profiles, target pests, use restrictions, formulation, and product specific information that affects actual risks to non-target species. In addition, the PCEA does not evaluate or differentiate risks from those products and uses that are "restricted use" from those that are "general use", although the very purpose of the "restricted use" classification is to mitigate potential risks.
6. Results of the "Comparative Analysis Model" are significantly flawed because for many of the endpoints evaluated, there were missing data for one or more of the active ingredients, or data was not generated for the same species or under standardized protocols, and thus are not directly comparable.

The lack of data for some active ingredients may not change the overall risk rankings for the highest ranked rodenticides (brodifacoum, zinc phosphide, difethialone), but could easily influence the summary values shown in Table 46, the risk presumptions in Table 47, and the reader's overall assessment of risk for the individual rodenticides.

7. US.EPA discusses a number of factors that contribute to uncertainty in the risk assessment including missing data, data of variable quality, and specific use information. US.EPA also acknowledges that "Additional data to fill-in where data are missing or standardize data where the quality is variable, as well as specific use and exposure information will likely provide the greatest reduction in uncertainty for these analysis". However, US.EPA does not explain or discuss how it intends to reduce the uncertainty in this assessment.
8. US.EPA has prepared a tabular comparative rating of potential risks (Table 47) based upon a qualitative "weight-of-evidence" assessment in which data is evaluated and risks (primary and secondary) are assigned a rating of high, moderate, or low. US.EPA does not explain how this "weight-of-evidence" assessment was performed, how ratings were assigned, what the ratings mean (e.g. are these relative or absolute risks; should we expect effects on individuals or populations of birds and/or non-target mammals), or how the ratings will be used by the US.EPA in a regulatory context. For example, what is the relationship between a "high" risk rating as used in the PCEA and those considered as "unreasonable adverse effect on the environment" as defined in FIFRA§ 3(c)(5)?
9. US.EPA is inconsistent with its risk evaluations for chlorophacinone and diphacinone. In some cases US.EPA differentiates between bait strengths of 0.005% (50ppm) and 0.01%(100 ppm) in their analysis, but in other cases they do not (i.e. secondary risks to birds and non-target mammals), even when the data is available to do so (see Tables 12 and 13, 20 and 21). In the subjective risk presumptions/rating (i.e. high, moderate, low) in Table 47, US.EPA does not specify which bait strengths of chlorophacinone and diphacinone baits are being rated. However, in the PCEA text (page 95) US.EPA states "Distinctions cannot be made between the 50 ppm and 100 ppm chlorophacinone and diphacinone baits in the incident data, but the 100 ppm baits are likely to present greater risks than the 50 ppm baits". This conclusion is contrary to the results of the Comparative Analysis Model in Table 46, where summary values for the two bait strengths are almost identical and do not indicate a difference in risk.
10. US.EPA evaluation of primary risk does not take into account the dyes that are added to some rodent grain baits in order to deter consumption by birds. US.EPA analysis also assumes that all baits weight 0.2 g per pellet or kernel, despite the fact that there are significant differences in weight for different rodenticide products. California Department of Food and Agriculture baits weigh approximately 0.025g per kernel or almost 10-fold less than assumed by US.EPA. This greatly reduces the potential primary risks of these baits to birds and non-target mammals compared to other baits evaluated by the PCEA.

If you have any questions, please contact me 559-582-3211, ext. 2830 or by e-mail, lwright@co.kings.ca.us.

Sincerely,

Dennis F. Bray
Agricultural Commissioner
Sealer of Weights and Measures

By:

Les Wright
Deputy Agricultural Commissioner
Sealer of Weights and Measures